# Iatrogenic Colorectal Anastomotic Leak Model in Swine for Studies Related to Early Diagnosis of Complications

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Introduction

Colorectal anastomotic leakage (CAL) is a devastating postoperative complication that significantly increases patient morbidity and mortality.[1] Limited knowledge is available to describe the pathophysiology associated with this postoperative complication, likely attributable to the fact that the anastomotic healing process is not yet fully understood.[2] Currently, there are very few models that simulate this complication with a clinically relevant approach. This restricts experimental research, making it difficult to introduce novel treatment strategies or early detection techniques in order to decrease the risk of CAL.[2]

NERv Technology Inc., a medical device company that has developed a solution for early leak detection of CAL, introduces a novel method for production on an iatrogenic clinically relevant leak in gastrointestinal anastomoses. This technique allows for controlled postoperative induction of CAL in a porcine model.[3] The aim of this study is to assess the effectiveness of the model proposed.
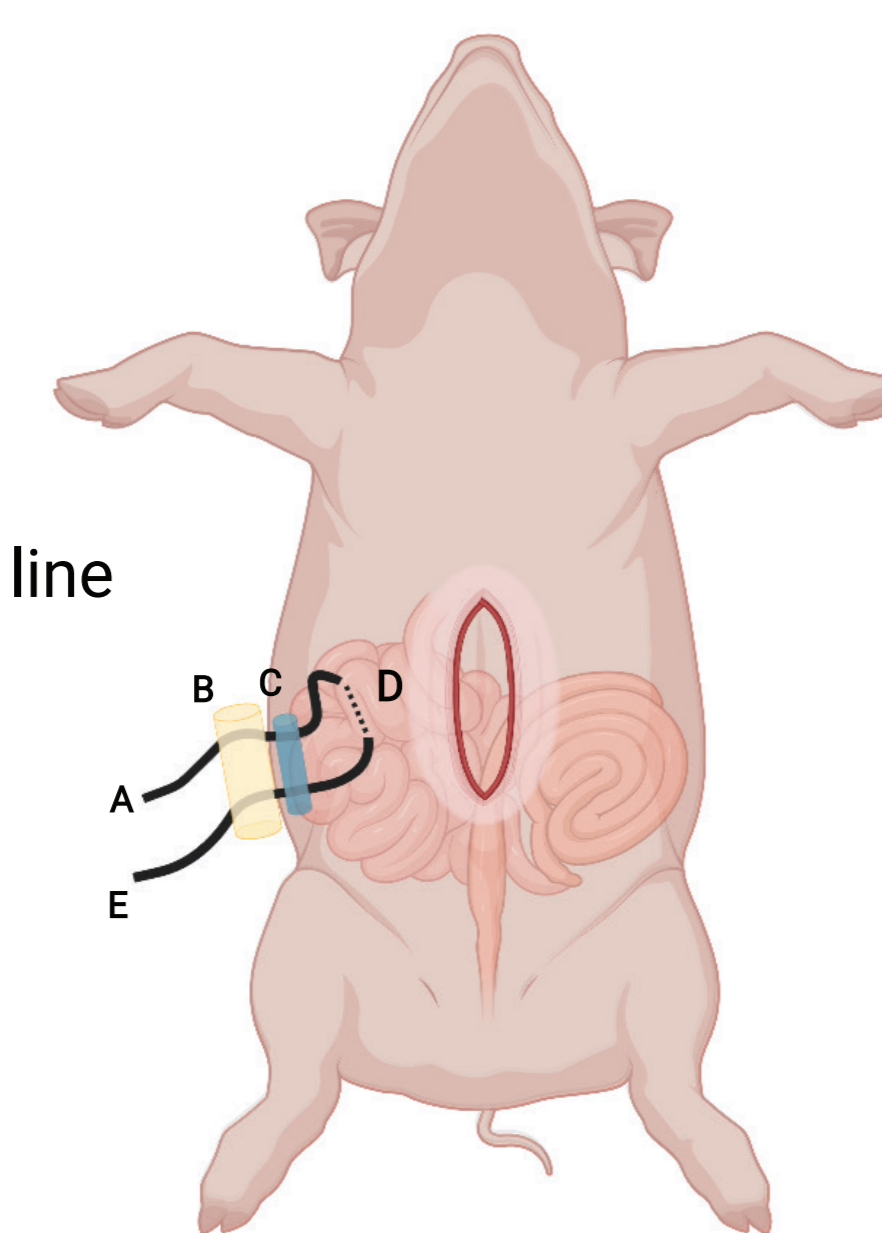
A Proximal end of pull-out suture
B Sterile Tube to secure exteriorized suture line
C Intra-abdominal sterile plastic film
D Suture line used to create anastomosis
E Distal end of pull-out suture

Methods

A 10 cm lower midline incision was performed

An enterotomy on the right colon that spanned 80% of the total circumference was created with electrocautery

A sterile plastic film was interposed between the parietal peritoneum and the anastomosis to prevent adhesion to the lateral abdominal wall

The exteriorized suture ends were tied to a latex tube to maintain tautness of the suture and the integrity of the anastomosis
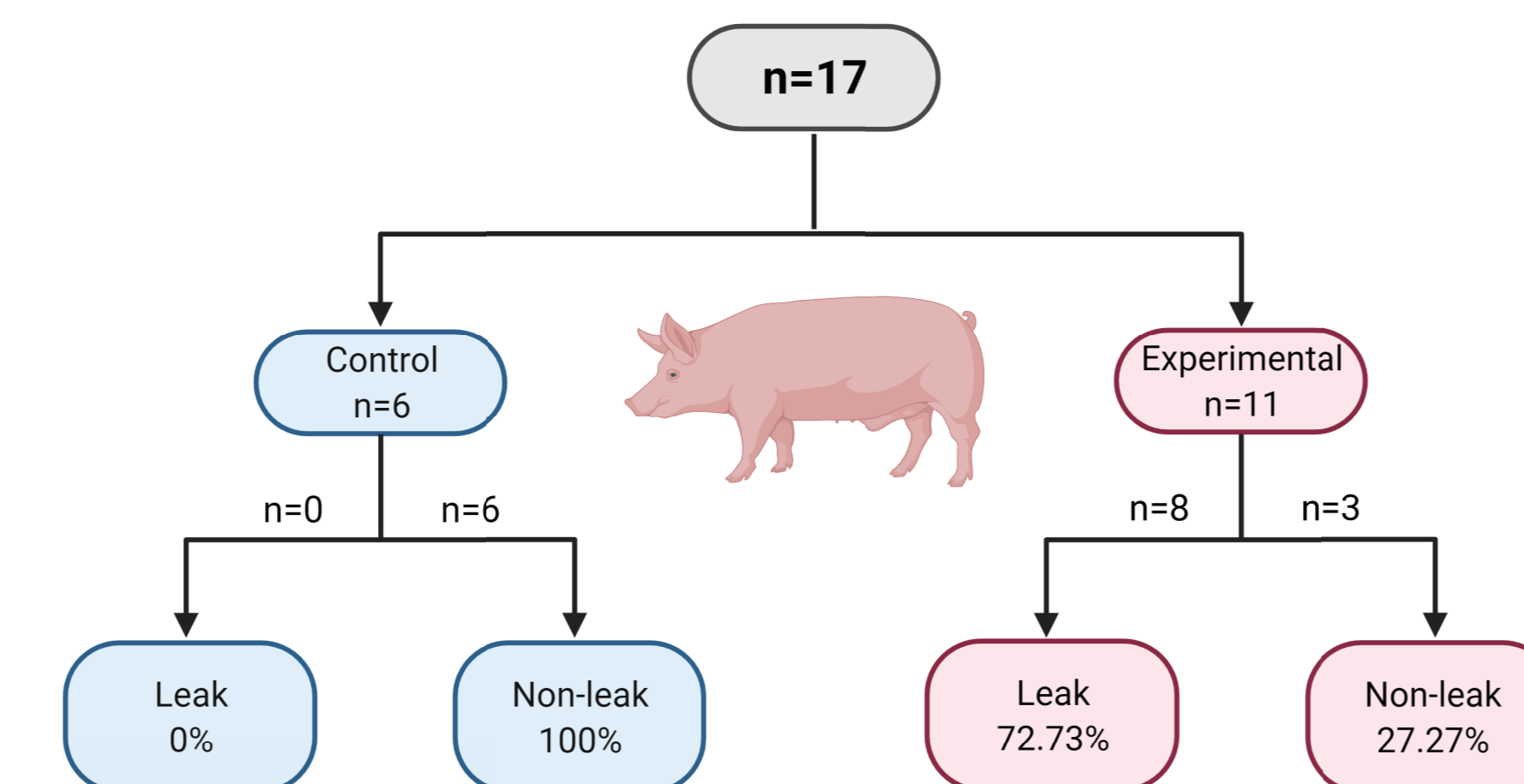
The exteriorized suture was cut 3-4 hours after the procedure in the experimental group. The latex tube was removed, and the suture was pulled to create an anastomotic breakdown

A relaparotomy was conducted upon presentation of CAL symptoms to assess for CAL and peritonitis

Results

All pigs were under 24-hour surveillance via a live feed for the qualitative assessment of behavioral indicators of CAL including lethargy, loss of appetite, emesis, discomfort, and signs of pain.

	Lethargy	Loss of appetite	Signs of pain/discomfort	Emesis
Experimental	54.5%	54.5%	45.5%	27.3%
Control	0%	0%	0%	0%
p-value	0.012	0.012	0.025	0.080

Clinical and laboratory indicators of CAL were also evaluated including decreased potassium levels, leukocytosis, tachycardia, and fever.[4] Additionally, macroscopic indicators of leakage including enteric spillage, fecal odour, inflammation, and peritonitis were assessed during the relaparotomy for both groups.

	Enteric Spillage	Local Inflammation or Peritonitis	Fecal Odour
Experimental	54.5%	63.6%	54.5%
Control	0%	16.7%	0%
p-value	0.012	0.032	0.012

	Decreased Blood Potassium	Leukocytosis	Tachycardia	Fever
Experimental	54.5%	20.0%	42.9%	42.9%
Control	0%	16.7%	33.3%	0%
p-value	0.012	0.434	0.362	0.034

A two-sample test for equality of proportions was conducted for each variable to compare the experimental and control cohorts. Significant results (p-value < 0.05) are shown on the table as green highlights.

72.7% of pigs in the experimental group presented with at least three indicators of CAL. This was confirmed during the relaparotomy as complete anastomotic breakdown was seen in 63.6% (n=7) of animals in this cohort while 9.1% (n=1) had a partial anastomotic breakdown. 27.3% (n=3) of the experimental pigs did not show symptoms of CAL. The relaparotomy revealed that although the plastic film interposing between the anastomosis and the peritoneum reduced containment of the leak, the anastomotic sites were walled off and the leak was contained by surrounding viscera. In contrast, 83.3% (n=5) of pigs in the control group had a normal postoperative recovery. One pig from that group had an incisional hernia observed during the relaparotomy, resulting in some local inflammation.

Conclusion

This porcine model allows for the simulation of a clinically significant iatrogenic leak with a 72.7% success rate and makes it possible to control the exact time of leak onset. This model will facilitate further experimentation on novel techniques for early detection, management, and treatment of leaks.

References

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